

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2002D–0468]

Guidance for Industry on the Manufacture and Labeling of Raw Meat Foods for Companion and Captive Noncompanion Carnivores and Omnivores; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the guidance for industry (#122) entitled “Manufacture and Labeling of Raw Meat Foods for Companion and Captive Noncompanion Carnivores and Omnivores.” The purpose of this document is to provide guidance on the manufacture and labeling of foods that contain raw meat, or other raw animal tissues, for consumption by dogs, cats, other companion or pet animals, and captive noncompanion animal carnivores and omnivores.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance document to the Communications Staff (HFV–12), Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit written comments on the guidance document to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://*

[//www.fda.gov/dockets/ecomments](http://www.fda.gov/dockets/ecomments). Comments should be identified with the full title of the guidance document and the docket number found in brackets in the heading of this document. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: William Burkholder, Center for Veterinary Medicine (HFV-228), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0179, e-mail: *William.burkholder@fda.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of December 18, 2002 (67 FR 77500), FDA published a notice of availability for a draft guidance entitled “Draft Guidance for Industry on Manufacture and Labeling of Raw Meat Foods for Companion and Captive Noncompanion Carnivores and Omnivores.” FDA gave interested persons until March 3, 2003, to comment. FDA considered all comments received and, where appropriate, incorporated them into the guidance.

II. Paperwork Reduction Act of 1995

According to the Paperwork Reduction Act of 1995, a collection of information should display a valid OMB control number. This guidance contains no collections of information.

III. Significance of Guidance

This level 1 guidance is being issued consistent with FDA’s good guidance practices regulation (21 CFR 10.115). The guidance represents the agency’s current thinking about the manufacture and labeling of raw meat foods for companion and captive noncompanion carnivores and omnivores. It does not create or confer any rights for or on any person and will not operate to bind

FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

IV. Comments

As with all of FDA's guidance, the public is encouraged to submit written or electronic comments on this guidance. FDA periodically will review the comments in the docket and, where appropriate, will amend the guidance.

Interested persons may, at any time, submit written or electronic comments to the Division of Dockets Management (see **ADDRESSES**) regarding this guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. A copy of the guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Electronic comments may be submitted on the Internet at *http://www.fda.gov/dockets/ecomments*. Once on this site, select [2002D-0468] "Manufacture and Labeling of Raw Meat Foods for Companion and Captive Noncompanion Carnivores and Omnivores" and follow the directions. Copies

of this guidance may be obtained on the Internet at *<http://www.fda.gov/cvm/guidance/published.htm>*.

Dated: May 12, 2004.

William K. Hubbard,

Associate Commissioner for Policy and Planning.

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